W. Steven Berman, Esquire
NJ Bar # 011971986
Napoli Shkolnik, & Assoc., PLLC
One Greentree Center, Suite 201
10,000 Lincoln Drive East
Marlton, NJ 08053
(856) 988-5574
Attorneys for Plaintiffs

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

---X

JOAN MULLIN,

Plaintiff,

v.

JANSSEN PHARMACEUTICALS, INC.; JANSSEN RESEARCH AND DEVELOPMENT, LLC; JOHNSON & JOHNSON CO; JANSSEN ORTHO, LLC; MITSUBISHI TANABE PHARMA CORP.; MITSUBISHI TANABE PHARMA HOLDINGS AMERICA, INC.; MITSUBISHI TANABE PHARMA DEVELOPMENT AMERICA, INC.; TANABE RESEARCH LABORATORIES U.S.A., INC.

Defendants.

---X

CIVIL ACTION

NO:

COMPLAINT AND JURY DEMAND

Plaintiff sues the Defendants named for compensatory and punitive damages and alleges as follows:

COMMON ALLEGATIONS

A. BACKGROUND

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of

Invokana (also known as canaglitlozin).

B. PARTIES

2. At the time of Plaintiff Evelyn Johnston's use of Invokana and injuries, Plaintiff was a resident and citizen of Kirksey, Kentucky. Plaintiff is presently a citizen of and resides in Kirksey, Kentucky.

3. Defendant Janssen Research & Development LLC ("Janssen R&D") is a limited liability company organized under the laws of New Jersey, with a principal place of business at 920 Route 202, Raritan, New Jersey 08869.

4. Janssen R&D's sole member is Janssen Pharmaceuticals, Inc.

5. Defendant Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with a principal place of business at 800 Ridgeview Drive, Horsham, Pennsylvania 19044.

6. Both Janssen, and its wholly owned LLC, Janssen R&D, are subsidiaries of Johnson & Johnson.

7. Janssen is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana. Janssen has intentionally transacted and conducted business within the State of New Jersey and has derived substantial revenue from goods and products disseminated and used in the State of New Jersey.

8. Defendant Johnson & Johnson, Inc. (J&J) is a New Jersey corporation with a principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

9. Defendant, JANSSEN ORTHO, LLC (hereinafter "Janssen Ortho") is a limited liability corporation organized under laws of Delaware whose registered agent for service of process is The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801. Janssen Ortho's principal place of business is at Stateroad 933 Km 0 1, Street Statero, Gurabo, Puerto Rico 00778.

10. Janssen Ortho is a subsidiary of Johnson & Johnson.

11. Janssen Ortho is engaged in the business of manufacturing, distributing, supplying, selling, marketing and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana. Janssen Ortho has intentionally transacted and conducted business within the State of New Jersey and has derived substantial revenue from goods and products disseminated and used in the State of New Jersey.

12. At all relevant times, Janssen Ortho manufactured Invokana.

13. Defendant Mitsubishi Tanabe Pharma Corp. ('Tanabe") is a Japanese corporation with its principal place of business at 3-2-10, Dosho- Machi, Chuo-ku, Osaka 541-8508, Japan.

14. TANABE is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana. Tanabe has intentionally transacted and conducted business within the State of New Jersey and has derived substantial revenue from goods and products disseminated and used in the State of New Jersey.

15. Defendant Mitsubishi Tanabe Pharma Holdings America, Inc. (Tanabe Holdings) is a Delaware corporation, with a principal place of business at 525 Washington Boulevard, Suite

400, Jersey City, NJ 07310.

16. Tanabe Holdings is a subsidiary of Tanabe and a holding company for U.S. subsidiaries.

17. Defendant Mitsubishi Tanabe Pharma Development America, Inc. (Tanabe Development) is a Delaware corporation, with a principal place of business at 525 Washington Boulevard, Suite 400, Jersey City, New Jersey 07310.

18. Tanabe Development licenses pharmaceuticals and drug therapies including Invokana for its parent corporation, Tanabe and conducts clinical development activity for obtaining marketing approval of drugs in the U.S., including Invokana, and provides administration support for the U.S. affiliates.

19. Defendant Tanabe Research Laboratories U.S.A., Inc. (Tanabe Research) is a California corporation, with a principal place of business 4540 Towne Centre Court, San Diego, California 92121.

20. Tanabe Research conducts pharmaceutical research, including with respect to Invokana.

21. Tanabe Research is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, its products, including the prescription drug Invokana. Tanabe has intentionally transacted and conducted business within the State of New Jersey and has derived substantial revenue from goods and products disseminated and used in the State of New Jersey.

22. At all times herein mentioned, Defendants advertised, promoted, supplied, and sold to distributors and retailers for resale to physicians, hospitals, medical practitioners, and the

general public a certain pharmaceutical product, Invokana, intentionally marketing and supplying the same in and to New Jersey and across the United States.

C. JURISDICTION AND VENUE

23. This Court has personal jurisdiction over the Defendants because they are either New Jersey entities, have principal places of business in New Jersey, have intentionally marked their products in New Jersey and/or have derived substantial revenue from their activities in New Jersey, including activities related to the allegations herein.

24. Further, this Court has jurisdiction over the parties pursuant to 28 U.S.C.A. §1332 because Plaintiff is not a citizen of New Jersey, Delaware, California, Pennsylvania nor Puerto Rico, where Defendants are incorporated or have their major places of business and the amount in controversy exceeds Seventy Five Thousand Dollars ($75,000.00), exclusive of interest and costs.

25. Pursuant to 28 U.S.C.A. §1391, venue is proper in this judicial district because several Defendants are located here and/or a substantial part of the events or omissions occurred within this federal judicial district.

26. At all times relevant to this action, Defendants engaged, either directly or indirectly, in the business of marketing, promoting, distributing, and selling prescription drug products, including Invokana, within New Jersey, with a reasonable expectation that the products would be used or consumed in this state, and thus regularly solicited or transacted business in this state.

27. At all times relevant to this action, Defendants were engaged in substantial business activities in Pennsylvania, including disseminating inaccurate, false, and misleading information about Invokana to health care professionals and patients in New Jersey, with a

reasonable expectation that such information would be used and relied upon by health care professionals and patients throughout New Jersey and throughout the United States.

D. FACTUAL ALLEGATIONS

28. Evelyn Johnston was prescribed, received and has taken the prescription drug Invokana. This action seeks, among other relief, general and special damages and equitable relief due to Plaintiff suffering severe and life-threatening side effects of kidney failure, heart attack and stroke, caused by ingesting this drug.

29. Invokana is a member of the glitlozin class of pharmaceuticals, also known as sodium- glucose co-transporter2 (“SGLT2”) inhibitors.

30. SGLT2 inhibitors, including Invokana, inhibit renal glucose reabsorption through the SGLT2 receptor in the proximal renal tubules, causing glucose to be excreted through the urinary tract. This puts additional stress on the kidneys in patients already at risk for kidney disease.

31. SGLT2 inhibitors, including Invokana, are designed to target primarily the SGLT2 receptor, but have varying selectivity for ther receptor, and block other sodium-glucose co-transporter receptors, including SGLT1.

32. The SGLT2 and SGLT1 receptors are located throughout the body, including in the kidney, intestines and brain.

33. Invokana has the highest selectivity for the SGLT1 receptor among SGLT2 inhibitors currently marketed in the United States.

34. SGLT2 inhibitors, including Invokana, are currently approved only for improvement of glycemic control in adults with type 2 diabetes.

35. At all times herein mentioned, the Defendants were engaged in the business of researching, licensing, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging and/or advertising for sale or selling the prescription drug Invokana for the use and application by patients with diabetes, including, but not limited to, Plaintiff.

36. Defendants Tanabe, Tanabe Holdings, Tanabe Development, and Tanabe Research, in collaboration with the other Defendants, designed developed, and marketed the diabetes drug, Invokana in the United States, and have made misrepresentations regarding the safety of the drug.

37. Defendant J&J, the parent company of the Janssen defendants, individually and through its subsidiaries, is involved in the marketing and branding of Invokana, and publishes marketing and warnings regarding the product.

38. Indeed, Defendants have published advertisements on their company websites and issued press releases announcing favorable information about Invokana. For example, the FDA's approval of Invokana on March 29, 2013 was announced on the J&J web site. On April 1, 2013,Tanabe announced the approval of Invokana in the United States as a new treatment option for Type 2 diabetes. On March 14, 2016, the J&J issued a press release announcing "First Real-World Evidence Comparing an SGLT2 Inhibitor with DPP-4 Inhibitors Shows Adults with Type 2 Diabetes Achieve Greater Blood Glucose Control with INVOKANA® (canagliflozin)". The former announcements did not contain warnings about ketoacidosis, serious infections, etc., while the latter announcement mentioned these conditions.

39. Through these advertisements, press releases, publications, and web sites, J&J has purposefully directed activities at residents of New Jersey.

40. The Invokana-related pages on the Defendants' web sites are accessible from within New Jersey, and have been indexed by search engines so that they are located through searches that are conducted from within New Jersey.

41. Defendant J&J also published information touting the strong sales of Invokana in its corporate reports and in earnings calls.

42. Further, J&J employees had responsibility for overseeing promotion strategies for the drug Invokana.

43. All marketing materials, advertisements, press releases, web site publications, dear doctor letters, and other communications regarding Invokana are part of the design and labeling of the drug, and could be altered without prior FDA approval.

44. Defendant J&J had the ability and the duty to independently alter the design and labeling of Invokana. Specifically, it could independently publish additional warnings regarding Invokana, particularly the propensity of the drug to cause diabetic ketoacidosis, renal injury, renal failure, severe infection, bone fracture, etc.

45. Defendant J&J so substantially dominates and controls the operations of Janssen, Janssen R&D, and Janssen Ortho, that it could have required them to make changes to the safety label of the drug Invokana.

46. J&J employees hold key roles in the design, development, regulatory approval, manufacturing, distribution, and marketing of Invokana and direct these activities on behalf of J&J, Janssen, Janssen R&D, and Janssen Ortho.

47. J&J so substantially dominates and controls the operations of Janssen, Janssen R&D, and Janssen Ortho, that the entities are indistinct for purposes of this litigation such that Janssen, Janssen R&D, and Janssen Ortho should be considered agents or departments of J&J,

and J&J is their alter-ego.

48. Employees of Tanabe, Tanabe Holdings, Tanabe Research, and Tanabe Development hold key roles in the design, development, regulatory approval, manufacturing, distribution, andmarketing of Invokana and direct these activities on behalf of J&J, Janssen, Janssen R&D, and Janssen Ortho.

49. On information and belief, Defendant Janssen Ortho failed to properly manufacture Invokana to ensure consistent quality with each batch that matched the (flawed) design specifications. The failure of consistent manufacture stemmed from faulty manufacturing processes, sub-par raw materials, and failure to properly clean and maintain equipment and other manufacturing facilities to ensure no cross-contamination from microbes and cleaning products.

50. On information and belief, manufacturing defects contributed to and caused injuries described elsewhere in this Complaint.

51. Defendant Janssen, a wholly owned subsidiary of J&J, acquired the marketing rights to Invokana in North America, and marketed, advertised, distributed, and sold Invokana in the United States, including New Jersey.

52. In May, 2012, Janssen R&D submitted a New Drug Application to the FDA for approval to market Invokana in the United States.

53. In March, 2013, the United States Food and Drug Administration ("FDA") approved Invokana as an adjunct to diet and exercise for the improvement of glycemic control in adults with type 2 diabetes.

54. As part of its marketing approval of Invokana, the FDA required required the defendants to conduct five post-marketing studies: a cardiovascular outcomes trial; and enhanced pharmacovigilance program to monitor for malignancies, serious cases of pancreatitis, severe

hypersensitivity reactions, photosensitivity reactions, liver abnormalities, and adverse pregnancy outcomes; a bone safety study; and two pediatric studies under the Pediatric Research Equity Act (PREA), including a pharmacokinetic and pharmacodynamics study and a safety and efficacy study.

55. In an effort to increase sales and market share, Defendants have aggressively marketed and continue to aggressively market Invokana to doctors and directly to patients for off-label purposes, including, but not limited to weight loss, reduced blood pressure, kidney benefits, cardiovascular benefits, and for use in type 1 diabetics

56. Defendants also, through their marketing material, misrepresented and exaggerated the effectiveness of Invokana, both as to its ability to lower glucose, and its benefit for non- surrogate measures of health, such as reducing adverse cardiovascular outcomes.

57. Defendants' marketing campaign willfully and internationally misrepresented the risks of Invokana and failed to warn about the risks of diabetic ketoacidosis, kidney failure and cardiovascular injury.

58. Defendants' misrepresentations and off-label advertising campaigns have led to Invokana being prescribed for off-label uses, in people with type 1 diabetes, for weight loss, and reduced blood pressure.

59. Invokana is one of Defendants' top selling drugs, with annual sales exceeding $1billion.

60. At all times herein mentioned, Defendants were authorized to do business within Delaware.

61. At all times herein mentioned, the officers and directors of Defendants participated in, authorized , and directed the production and promotion or the aforementioned

product when they knew, or with the exercise of reasonable care should have known, of the hazards and dangerous propensities of said product and thereby actively participated in the tortious conduct which resulted in the injuries suffered by Plaintiff herein.

62. Defendants misrepresented that Invokana is a safe and effective treatment for type 2 diabetes mellitus when in fact the drug causes serious medical problems which require hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, kidney failure and its sequelate, as well as serious cardiovascular problems.

63. Specifically, Defendants knew or should have known or the risks of diabetic ketoacidosis and kidney failure based on the data available to them or that could have been generated by them, including , but not limited to animal studies, mechanisms of action, pharmacodynamics, pharmacokinetics, pre-clinical studies, animal models, genetic models, analogous compounds, analogous conditions, adverse event reports, case reports, post0mnarketing reports, and regulatory authority investigations, including, but not limited to the following:

a. Invokana selectivity for the SGLT1 receptor;

b. Animal studies demonstrating increased ketones when given Invokana;

c. Studies of phlorizin indicating a propensity to cause ketoacidosis;

d. Reports involving people with familial glycosuria, indicating a propensity to develop ketoacidosis;

e. Clinical studies, adverse event reports, and case reports demonstrating increased ketones in people taking Invokana;

f. Clinical studies, adverse event reports, and case reports demonstrating increased ketones in people taking Invokana;

g. Clinical studies, adverse event reports, and case reports demonstrating dehydration and colume depletion in people taking Invokana;

h. Clinical studies, adverse event reports, and case reports demonstrating vomiting in people taking Invokana;

i. Clinical studies, adverse event reports, and case reports demonstrating re-challenge responses in increasing ketones and diabetic ketoacidosis in people taking Invokana;

j. Adverse event report analysis demonstrating an increased rate of reports for ketoacidosis in people taking Invokana compared to other glucose-lowering medications.

64. Diabetic Ketoacidosis may lead to complications such as cerebral edema, pulmonary edema, cerebrovascular accident, myocardial infarction, nonspecific myocardial injury, severe dehydration, and coma.

65. Invokana induced diabetic ketoacidosis may lead to delayed treatment because in many cases Invokana will keep blood sugar below 250 mg/dl, a threshold often used when diagnosing diabetic ketoacidosis. This may result in increases progression of the condition and increased injury to the patient.

66. Defendants were aware that the mechanism of action for Invokana places extraordinary strain on the kidneys and renal system.

67. Despite its knowledge of data indicating hat Invokana use is causally related to the development of diabetic ketoacidosis and kidney failure, Defendants promoted and marketed Invokana as safe and effective for persons such as Plaintiff throughout the United States, including Pennsylvania and Delaware.

68. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not warn patients but instead continued to defend Invokana, mislead physicians and the public, and minimize unfavorable findings.

69. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not warn patients but instead continued to defend Invokana, mislead physicians and the public, and minimize unfavorable findings.

70. Despite Defendants' knowledge of the increased risk of severe injury among Invokana users, Defendants did not conduct the necessary additional studies to properly evaluate these risks prior to marketing the drug to the general public.

71. Consumers of Invokana and their physicians relied on the Defendants' false representations and were misled as to the drug's safety, and as a result have suffered injuries including diabetic ketoacidosis, kidney failure, cardiovascular problems, and the life-threatening complications thereof.

72. Consumers, including Plaintiff, have several alternatives safer methods for treating diabetes, including diet and exercise and other antidiabetic agents

73. Plaintiff was prescribed Invokana by his treating physician and used it as directed.

74. Plaintiff was first prescribed Invokana in order to treat her diabetes on or about January, 2015.

75. While taking Invokana, Plaintiff developed and suffered a Heart attack, Kidney Failure, Ketoacidosis and a Stroke, and other injuries as a result of Plaintiff's ingestion of Invokana.

76. As a result of Plaintiffs' Invokana related injuries, Plaintiff developed serious complications which required multiple days of hospitalization.

77. Plaintiff has endured pain and suffering, emotional distress, loss of enjoyment of life, and economic loss, including significant expenses for medical care and treatment which will continue in the future. Plaintiff seeks actual, compensatory, and punitive damages from Defendants.

78. Defendants' wrongful acts, omissions, and fraudulent misrepresentations caused Plaintiff's injuries and damages.

79. Defendants misrepresented that Invokana is a safe and effective treatment for type 2 diabetes mellitus when in fact the drug causes serious medical problems which require hospitalization and can lead to life threatening complications, including but not limited to diabetic ketoacidosis and its sequelae, kidney failure and its sequelae, as well as serious cardiovascular problems.

80. Plaintiff's injuries were preventable and resulted directly from Defendants' failure and refusal to conduct proper safety studies, failure to properly assess and publicize alarming safety signals, suppression of information revealing serious and life-threatening risks, willful and wanton failure to provide adequate instructions, and willful misrepresentations concerning the nature and safety of Invokana. This conduct and the product defects complained of were substantial factors in bringing about and exacerbating Plaintiff' injuries.

81. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and his physicians the true and significant risks associated with taking Invokana.

82. On information and belie, Defendants withheld material information from the FDA and misrepresented material information regarding the risks and benefits of Invokana in its communications with the FDA. These omissions and misrepresentations included failing to report instances of diabetic ketoacidosis to the FDA, failure to properly categorize adverse events in clinical trials, post-marketing trials, and obtained through its adverse event reporting system, and withholding of relevant information from pre-clinical and clinical trials.

83. On May 15, 2015 the FDA announced that SGLT2 inhibitors may lead to diabetic ketoacidosis.

84. On September 10, 2015, the FDA announced that Invokana causes premature bone loss and fractures.

85. On October 16, 2015, Health Canada, the Canadian drug regulatory authority, announced that Invokana can cause acute kidney injury.

86. On December 4, 2015, the FDA announced a label change for SGLT2 inhibitors, requiring that the label of SGLT2 inhibitors include a warning of ketoacidosis, the risk of too much acid in the blood while taking SGLT2 inhibitors.

87. Prior to the FDA's December 4, 2015 safety announcement, Invokana's label continued to fail to warn consumers of the serious risk of developing diabetic ketoacidosis.

88. The Invokana label currently does not warn of the serious risks of developing bone fractures and kidney injury.

89. Despite the FDA's announcements, Defendants continue to engage in aggressive direct-to-consumer and physician marketing and advertising campaigns for Invokana.

90. Defendants failed to ensure that full and correct safety labeling and warnings were used in pharmacy sheets that accompanied Invokana to the purchaser.

91. At all times mentioned herein, Defendants knew, or in the exercise of reasonable care should have known, that Invokana was such a nature that it was not properly designed, manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared, and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the product's users.

92. Defendants had a duty to warn Plaintiff's prescribing physicians about the risks of Invokana use, including the risk of diabetic ketoacidosis and resulting complications.

93. Had Plaintiff and his physicians known the true risks associated with the use of SGLT2 inhibitors, including Invokana, Plaintiff would not have been prescribed Invokana, and Plaintiff would not have taken Invokana, or Plaintiff would have been adequately monitored for its side effects and as a result would not have suffered injuries and damages from using Invokana.

94. Plaintiff's prescribing and treating physicians relied on claims made by Defendants that Invokana has been clinically shown to improve glycemic control and was generally safe and effective. These claims reached Plaintiff's prescribing and treating physicians directly, through print and television advertising, articles and study reports funded and promoted by Defendants, and indirectly, through other healthcare providers and others who have been exposed to Defendants' claims through its comprehensive marketing campaigns.

95. Plaintiff relied on claims made by Defendants that Invokana has been clinically

shows to improve glycemic control and was generally safe and effective. These claims reached Plaintiff directly, through print and television advertising, and indirectly through Plaintiff's healthcare providers and others who have been exposed to Defendant's claims through its comprehensive marketing campaigns.

96. Based on Defendants' direct-to-consumer advertising and Defendants' misrepresentations and omissions, Plaintiff made an independent decision to use Invokana based on the overall benefits and risks communicated by Defendants.

97. Plaintiff's injuries were a reasonably foreseeable consequence of Defendants' conduct and Invokana's defects, and were not reasonably foreseeable to Plaintiff of Plaintiff's physicians.

98. As a As a foreseeable, direct, and proximate consequence of Defendants' actions, omissions, and misrepresentations, Plaintiff suffered injury. In addition, Plaintiff requires and will continue to require healthcare and services. Plaintiff has incurred and will continue to incur medical and related expenses. Plaintiff also has suffered and will continue to suffer diminished capacity for the enjoyment of life, diminished quality of life, increased risk of premature death, aggravation of pre existing conditions, activation of latent conditions, and other losses and damages. Plaintiff's direct medical losses and costs include physician care, monitoring, and treatment. Plaintiff has incurred and will continue to incur mental and physical pain and suffering.

99. Plaintiff files this lawsuit within the applicable limitations period of the first suspecting that Invokana caused the appreciable harm sustained by Plaintiff. Plaintiff could not, by the exercise of reasonable diligence, have discovered the wrongful cause of Plaintiff's injuries

as their cause was unknown to Plaintiff. Plaintiff did not suspect, nor did Plaintiff have reason to suspect, that he had been injured, the cause of the injuries, or the tortious nature of the conduct causing the injuries, until less than the applicable limitations period prior to the filing of this action. Additionally, Plaintiff was prevented from discovering this information sooner because Defendants misrepresented and continue to misrepresent to the public and to the medical profession that the drug Invokana is safe and free from serious side effects, and Defendants have fraudulently concealed facts and information that could have led Plaintiff to discover a potential cause of action.

E.CAUSES OF ACTION

COUNT I – DESIGN DEFECT

100. Defendants designed, developed, researched, tested, licensed, manufactured, packaged, labeled, promoted, marketed, sold, and distributed Invokana in a defective and unreasonably dangerous condition, including the Invokana used by plaintiff.

101. The design defect made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

102. The design defect was such that the risks of Invokana outweighed its utility.

103. There were practical and technically feasible alternative designs that would not have reduced the utility of Invokana and would not have cost substantially more to develop, including, but not limited to providing a better warning with Invokana, using an alternative diabetes treatment, or developing an SLGT2 inhibitor with a different safety profile.

104. Defendants' defective design of Invokana was reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Defendants made conscious decisions not to redesign, adequately warn, or inform the unsuspecting public. Defendants' reckless conduct warrants and award of punitive damages. Defendants' conduct was motivated by greed and the intentional decision to value profits over te safety and well-being of the consumers of Invokana.

105. Plaintiff was prescribed and used Invokana for its intended purposes and for purposes that Defendants expected and could foresee.

105. Defendants expected and intended Invokana to reach, and it did in fact reach, Plaintiff without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

106. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known of the design defects.

107. Plaintiff and Plaintiff's physicians did not have the same knowledge or expertise as Defendants and could not have discovered any defect in Invokana through the exercise of reasonable care.

108. As a direct and proximate cause of Defendants; manufacture, sale and promotion of the defectively designed drug, Plaintiff sustained permanent injury.

109. The defects in Invokana were substantial contributing factors in causing Plaintiff's injuries.

COUNT II –FAILURE TO WARN

110. The Defendants are liable under the theory of strict product liability as set forth in the New Jersey Product Liability act, and/or other applicable law.

111. Defendants designed, developed, researched, tested, licenses, manufactured, packaged, labeled, promoted, marketed, sold, and distributed Invokana in a defective and unreasonably dangerous condition, including the Invokana used by Plaintiff. The design defect made Invokana more dangerous than an ordinary consumer would expect and more dangerous than other drugs used to treat diabetes.

112. Invokana's inadequate warning rendered Invokana unreasonably dangerous and defective.

113. Defendants' defective warnings for Invokana were reckless, willful, wanton, fraudulent, malicious, and done with reckless disregard for the health and safety of users of Invokana. Defendants' made conscious decisions not to adequately warn about risks they know or should have known about. Defendants' reckless conduct warrants an award of punitive damages. Defendants' conduct was motivated by greed and the intentional decision to value profits over the safety and well-being of the consumers of Invokana.

114. Plaintiff was prescribed and used Invokana for its intended purposes and for purposes that Defendants expected and could foresee.

115. Defendants expected and intended Invokana to reach, and it did in fact reach, Plaintiff without any substantial change in the condition of the product from when it was initially manufactured by Defendants.

116. Plaintiff could not have discovered the unwarned of risks of using Invokana through the exercise of reasonable care.

117. Defendants, as manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field, and further, Defendants knew or should have known that the warnings and other relevant information and data which they distributed regarding the risks of injuries and death associated with the use of Invokana were incomplete and inadequate.

118. Plaintiff did not have the same knowledge as Defendants and no adequate warning or other clinically relevant information and data was communicated to Plaintiff or to Plaintiff's treating physicians. The warnings that were given by the Defendants were not accurate and were incomplete.

119. Defendants had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, supply, warn, and take other such steps as necessary to ensure that Invokana did not cause users to suffer from unreasonable and dangerous risks.

120. Defendants knew or should have known that the limited warnings disseminated with Invokana were inadequate, but they failed to communicate adequate information on the dangers and safe use of its product, taking into account the characteristics of and the ordinary knowledge common to physicians who would be expected to prescribe the drug. In particular, Defendants failed to communicate warnings and instructions to doctors that were appropriate and adequate to render the product safe for its ordinary, intended, and reasonably foreseeable uses, including the common, foreseeable, and intended use of the product for treatment of diabetes.

121. As a direct and proximate cause of Defendants' manufacture, sale and promotion of the defectively designed drug and failure to warn Plaintiff and her physicians about the significant risks inherent in Invokana therapy, Plaintiff sustained severe injury.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT III –NEGLIGENCE

122. Plaintiff hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

123. The Defendants were negligent in marketing, designing, manufacturing, packaging, labeling, supplying, inspecting, testing, selling and/or distributing the PRODUCTS in the following ways, each of which was a proximate cause of Plaintiff's injuries and damages:

a) In failing to warn Plaintiff of the hazards associated with the use of their product, including the risk of ovarian cancer when the product is used in the genital area, in the perineal area or on sanitary napkins.

b) In failing to properly test their products to determine adequacy and effectiveness or safety measures, if any, prior to releasing these products for consumer use;

c) In failing to properly test their products to determine the increased risk of ovarian cancer during the normal and/or intended use of the products;

d) In failing to inform ultimate users, such as Plaintiff as to the safe and proper methods of handling and using their products;

e) In failing to remove their products from the market or adding proper warnings when the Defendants knew or should have known their products were defective;

f) In failing to instruct the ultimate users, such as Plaintiff, as to the methods for reducing the type of exposure to the Defendants' products which caused increased risk in ovarian cancer;

g) In failing to inform the public in general and the Plaintiff in particular of the known dangers of using the Defendants' products for dusting the perineum;

h) In failing to advise users how to prevent or reduce exposure that caused increase risk for ovarian cancer;

i) Marketing and labeling their product as safe for all users despite knowledge to the contrary;

j) In failing to act like a reasonably prudent company under similar circumstances.

124. Each and all of these acts and omissions, taken singularly or in combination, were a proximate cause of the injuries and damages sustained by Plaintiff.

125. At all pertinent times, the Defendants knew or should have known that the products were unreasonably dangerous and defective when put to their reasonably anticipated use.

126. As a direct and proximate result of Defendants' negligence, Plaintiff purchased and used Invokana which caused Plaintiff's injuries, medical bills and conscious pain and suffering;

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT IV –BREACH OF EXPRESS WARRANTY

127. Plaintiff adopts by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

128. At all relevant times, Defendants expressly represented and warranted to Plaintiff and Plaintiff's physicians and health care providers, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts, marketing , and other written materials intended for physicians, medical patients and the general public, that Invokana was safe, effective, fit and proper for its intended use, of merchantable quality, had been adequately tested, contained, adequate warning, and was emcacious.

129. In particular, the "Warnings and Precuations" section of the Invokana prescribing information purports to expressly describe the relevant and material potential side-effects that Defendants knew or should have known about.

130. In particular the Consumer Medication Guide expressly indicated " What is the most important information I should know about Invokana?" and" What are the possible side effects of Invokana?" and "General information about the safe and effective use of INVOKANA and does not mention that Invokana has been associated with diabetic Ketoacidosis, kidney failure, or cardiovascular adverse events.

131. Plaintiffs physician prescribed Invokana and Plaintiff consumed Invokana reasonably replying upon these warranties. Plaintiff and Plaintiff's physicians did not know and could not have learned independently that Defendants' representations were false and misleading.

132. Defendants knew and expected, or should have known and expected, and intended Plaintiff to reply on their warranties.

133. The representations contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises

134. In utilizing Invokana, Plaintiff reasonably relied on the skill, judgment, representations and foregoing warranties of Defendants.

135. These warranties and representations were false in that Invokana is not safe, effective, fit and property for its intended use because of its propensity to cause, among other conditions, diabetic ketoacidosis, kidney failure, and cardiovascular problems.

136. Because Invokana did not conform to the Defendants' express representation, Defendants breached the warranties.

137. As a foreseeable, direct, and proximate result of the breach of express warranties by Defendants breached the warranties.

COUNT V- BREACH OF IMPLIED WARRANTY

138. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

139. At the time the Defendants designed, manufactured, assembled, fabricated, labeled, packaged, sold and/or distributed the products, the Defendants knew of the uses for which the products were intended, and impliedly warranted the products to be of merchantable quality and safe for such use.

140. The Defendants, as sellers were merchants with respect to the products which they sold.

141. Defendants sold these products in a defective condition and therefore breached an implied warranty of fitness and an implied warranty of merchantability. Additionally, Defendants breached their implied warranties of the products sold to Plaintiff because the products were not fit for their common, ordinary and intended uses.

142. Therefore the Defendants have breached the implied warranty or merchantability as well as the implied warranty of fitness for a particular purpose law. Such breach by the Defendants was a proximate cause of the injuries and damages sustained by Plaintiff.

143. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff purchased and used the products that caused Plaintiff's injuries; incur medical bills and conscious pain and suffering.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT VI- GROSS NEGLIGENCE

144. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

145. The Defendants' conduct was in conscious disregard for the rights, safety and welfare of the Plaintiff. The Defendants acted with willful and wanton disregard for the safety of the Plaintiff. The Defendants' conduct constitutes gross negligence.

Defendants' gross negligence was a proximate cause of Plaintiff's injuries, and as such the Defendants are liable for exemplary and punitive damages.

146. The Johnson and Johnson Defendants have a pattern and practice of this type of conduct. Specifically, these Defendants built their company on the credo, "We believe our first responsibility is to the doctors, nurses, and patients, to mothers and fathers and all others who use our products and services." The Defendants places emphasis on shareholders believing that if they take care of everything the ethical and correct way profits will follow. However, over the past few decades, the Defendants have sharply deviated from their original credo, and instituted a corporate pattern and practice of placing profits over the health and well-being of its customers as evidenced in the Propulsid™ litigation, Ortho Evra™ litigation, 2006 Pennsylvania Tylenol™ litigation, 2006 TMAO investigation, and 2007 violation of the Foreign Corrupt Practices Act.

147. The above listed evidence indicated a pattern and practice of Johnson & Johnson Defendants to place corporate profits over health and well-being of is customers. Such a pattern and practice has been followed by the Defendants regarding Invokana.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT VII- FRAUDULENT MISREPRESENTATION

148. Plaintiff adopts by reference each and every paragraph of this Complaint as if full copied and set forth at length herein.

149. Defendants intentionally and fraudulently misrepresented the safety and efficacy of Invokana in the product label and through its marketing activities.

150. In Particular, Defendants intentionally and fraudulently:

a. Failed to adequately warn about the risk of diabetic ketoacidosis;

b. Failed to provide full and complete information about Invokana to the FDA;

c. Provided a product label to Plaintiffs physicians that did not adequately disclose the risks that Defendants knew of;

d. Provided consumer information that did not adequately disclose the risks that Defendants knew of;

e. Overstated the benefits of Invokana; and

f. Marketed Invokana for unapproved uses such as weight loss and lowering blood pressure.

151. The representations were made by the Defendants with the intent that doctors and patients, including Plaintiff and Plaintiffs physicians, rely upon them, in willful, wanton, and reckless disregard for the lack of truthfulness of the representations and with the intent to defraud and deceive Plaintiff and Plaintiffs physicians.

152. Plaintiff and Plaintiffs physicians reasonably relied on the fraudulent misrepresentations both as communicated to them directly from Defendants and as communicated to them by others exposed to Defendants' pervasive marketing campaigns.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT VII- NEGLIGENT MISREPRESENTATION

153. Plaintiff adopts by reference each and every paragraph of this Complaint as if fully copied and setforth at length herein.

154. From the time lnvokana was first tested, studied, researched, evaluated, endorsed, manufactured, marketed and distributed, and up to the present, Defendants made misrepresentations to Plaintiff, Plaintiffs physicians and health care providers, and the general public, including but not limited to the misrepresentation that Invokana was safe, fit, and effective for human consumption.

155. Defendants owed a duty to Plaintiff to exercise reasonable care to ensure they did not misrepresent the safety or efficacy of Invokana nor create unreasonable risks of injury to others, and failed to exercise that reasonable care and therefore breached their duty.

156. The defendants made the foregoing misrepresentations without any reasonable grounds for believing them to be true, and were in fact, reckless

157. The Defendants had a duty to correct these material misstatements because they knew or should have known that they were inaccurate and that others would reasonably rely on them and suffer injury.

158. These misrepresentations were made directly by Defendants, by sales representatives and other authorized agents of Defendfants, and in publications and other written materials directed to physicians, medical patients and the public, with the intention of inducing reliance and the prescription, purchase and use of the subject product.

159. The representations by the Defendants were in fact false, in that Invokana is not safe, fit and effective for human consumption, using Invokana is hazardous to health, and Invokana has a serious propensity to cause serious injuries to users, including but not limited to the injuries suffered by plaintiff.

160. The foregoing representations by Defendants were made with the expectation and intention of inducing reliance upon them and increasing the prescription, purchase and use of Invokana.

161. Plaintiff reasonably relied on the misrepresentations made by the Defendant to their detriment.

162. In reliance of the misrepresentations by the Defendants, and each of them, Plaintiff was induced to purchase and use Invokana.

163. If Plaintiff had known of the true facts and the facts concealed by the Defendants, Plaintiff would not have used Invokana.

164. The reliance of Plaintiff upon Defendants' misrepresentations was justified because such misrepresentations were made and conducted by individuals and entities that were in a position to know the true facts.

165. As a direct, proximate, and foreseeable result of Defendants' negligent misrepresentations, Plaintiff suffered injuries and damages as alleged herein.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT VIII- FRAUDULENT CONCEALMENT

166. Plaintiff adopts by reference each and every paragraph of this Complaint as if fully copied and set forth at length herein.

167. At all relevant times, Defendants knew that Invokana was defective, unreasonably unsafe, and that its risks were understated and its benefits were overstated.

168. Defendants willfully, intentionally and fraudulently concealed their knowledge of this from Plaintiffs', Plaintiff's physicians, and the public, and instead knowingly provided false information.

169. Defendants withheld information that they had a duty to disclose through Invokana's labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Invokana was safe and effective.

170. Defendants withheld information about the severity of the substantial risks of using Invokana and their knowledge of the safety signals regarding adverse effects of Invokana

171. Defendants withheld information that Invokana was not safer or more effective than alternative diabetes medications available on the market.

172. The above facts were material would have been considered important to a reasonable person.

173. Had the above facts been disclosed, they would have changed Plaintiffs decision to take Invokana and Plaintiffs physician's decision to provide sampled of it.

174. Defendants had a duty to disclose this information to Plaintiff and Plaintiffs physicians.

175. Defendants had sole access to material facts concerning, and unique and special knowledge and expertise regarding, the dangers and unreasonable risks of Invokana.

176. Defendants knew or should have known and expected or should have expected and intended that Plaintiff and Plaintiffs physicians rely on the inaccurate information they provided.

177. As a foreseeable, direct, and proximate result of Defendants' actions and fraudulent concealment, Plaintiff suffered injury.

COUNT IX- CONCERT OF ACTION

(All Defendants)

178. Plaintiffs hereby incorporate by reference each of the preceding paragraphs as if fully set forth herein.

179. At all pertinent times, Defendants knew or reasonably should have known that the Invokana should contain warnings of the risks of severe and life-threatening side effects of kidney failure, heart attack and stroke, caused by this drug , but purposefully sought to suppress such information and omit it from the product so as not to negatively affect sales and maintain the profits of the Defendants.

180. Additionally and/or alternatively, the Defendants aided and abetted each other in the negligence, and reckless misconduct. Pursuant applicable law, each of the Defendants is liable for the conduct of the other Defendants for whom they aided and abetted.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

COUNT IX – PUNITIVE DAMAGES
(N.J.S.A. 2A: 58C-1;, N.J.S.A. 2A:15-5.9, et seq.,)

181. Plaintiffs incorporate by reference all preceding paragraphs as if fully set forth herein.

182. The Defendants have acted willfully, wantonly, with an evil motive, and/or recklessly in one or more of the following ways:

a. Defendants knew of the unreasonably high risk of injuries posed by Invokana before manufacturing, marketing, distributing and/or selling Invokana, yet purposefully proceeded with such action;

b. Despite their knowledge of the high risk of injuries associated with Invokana, Defendants affirmatively minimized this risk through marketing and promotional efforts and product labeling;

c. Through the actions outlined above, Defendants expressed a reckless indifference to the safety of users of Invokana, including Plaintiffs, Defendants' conduct, as described herein, knowing the dangers and risks of Invokana, yet concealing and/or omitting this information in furtherance of their conspiracy and concerted action was outrageous because of Defendants' evil motive or a reckless indifference to the safety of users of Invokana.

183. The acts, conduct and omissions of Defendants, as alleged throughout this Complaint were willful and malicious. Defendants committed these acts with a conscious disregard for the rights, health and safety of Plaintiff and other Invokana users and for the primary purpose of increasing

Defendants' profits from the sale and distribution of Invokana. Defendants' outrageous and unconscionable conduct warrants an award of exemplary and punitive damages against Defendants in an amount appropriate to punish and make an example of Defendants.

184. Despite their knowledge, Defendants, acting through their officers, directors and managing agents, for the purpose of enhancing Defendants' profits, knowingly and deliberately failed to remedy the known defects in Invokana and failed to warn the public, including Plaintiff of the extreme risk of injury occasioned by said defects inherent in Invokana. Defendants and their agents, officers, and directors intentionally proceeded with the manufacturing, sale, distribution, and marketing of Invokana knowing these actions would expose persons to serious danger in order to advance Defendants' pecuniary interest and monetary profits.

185. Defendants' conduct was despicable and so contemptible that it would be looked down upon and despised by ordinary decent people, and was carried on by Defendants with willful and conscious disregard for the safety of Plaintiff and other consumers, entitling Plaintiff to exemplary damages.

WHEREFORE, Plaintiffs pray for judgment against Defendants for compensatory, treble and punitive damages, together with interest, cost of suit, attorneys' fees and such further and other relief as the Court deems just and appropriate.

WHEREFORE, Plaintiffs demand judgment against Defendants for compensatory, treble, and punitive damages, together with interest; costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

JURY TRIAL DEMANDED

WHEREFORE, Plaintiffs demand that all issues of fact of this case be tried to a properly impaneled jury to the extent permitted under the law.

Dated: September 2, 2016

Napoli Shkolnik, PLLC

By: W. Steven Berman

W. Steven Berman, Esquire
NJ Bar # 011971986
One Greentree Center, Suite 201
10,000 Lincoln Drive East
Marlton, NJ 08053
(856) 988-5574
Attorneys for Plaintiffs